UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Jacob Leibowitz,	)	Case No.: _____
Plaintiff,	)	
v.	)	**Plaintiff's Complaint And Jury Demand**
Smith & Nephew, Inc. ,	)	
Defendants	)	

PLAINTIFF'S COMPLAINT AND JURY DEMAND

Plaintiff, by and through counsel, Davis, Saperstein & Salomon P.C., upon information and belief, at all times hereinafter mentioned, alleges as follows:

1. This Complaint is brought on behalf of Plaintiff Jacob Leibowitz, who suffered damages as a direct and proximate result of the Defendant's negligent and wrongful misconduct in connection with the development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, and sale of the Smith & Nephew Trigen Intertan Nail, Internal Hex Captured Screw and Integrated Interlocking Lag Screw [collectively, the "Trigen Intertan Nail" or "Product"].

PARTIES

2. Plaintiff Jacob Leibowitz is a resident and citizen of Monsey, Rockland County, New York.

3. Defendant SMITH & NEPHEW, INC. is a company engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, advertising, marketing, distributing, labeling, and selling medical devices, including the Product described above.

4. Defendant SMITH & NEPHEW, INC. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware with offices located in 1450

Brooks Road, Memphis, Tennessee 38116. Defendant SMITH & NEPHEW, INC. transacts business around the world, in the United States, and in the State of New York.

5. Defendant SMITH & NEPHEW, INC. marketed the Product in the U.S. after it was approved by the Food and Drug Administration ("FDA") as "substantially equivalent to legally marketed predicate devices" on February 20, 2004.

6. Defendant SMITH & NEPHEW, INC. is a U.S. subsidiary of Smith & Nephew PLC.

7. Defendant SMITH & NEPHEW, INC. is hereinafter referred to as "Smith & Nephew," or "Defendant."

JURISDICTION AND VENUE

8. This court has subject matter jurisdiction under 28 U.S.C. § 1332, based on diversity of citizenship between the parties, and the amount in controversy exceeding $75,000 (seventy-five thousand dollars) exclusive of interest and costs.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) and (c), as Plaintiff fell and fractured his hip and had all of his relevant medical care and treatment in this district, and the Defendant conducts business and sales activity in this district. Thus, the Defendant is subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

A. Hip Fracture Repair

10. Falls among the elderly and infirm are an unfortunate but common fact of life that can cause various types of fractures to the femur. For certain types of these fractures, orthopedic devices known generally as intramedullary nails are used to fix the position of broken bone fragments.

11. During surgical repair of one type of hip fracture known as an intertrochanteric fracture of the head of the femur, a nail is driven down the interior of the femoral shaft, while interlocking screws are driven into the femoral neck and femoral head to fix the bone fragments into proper anatomic position. Defendants' Product is one of a class of essentially similar orthopedic devices used to repair such fractures.

B. Plaintiff's Implant Surgery

12. Plaintiff, Jacob Leibowitz, was born on December 1, 1929.

13. On or about September 21, 2013, Plaintiff fell and suffered an intertrochanteric fracture of his right hip for which he underwent orthopedic surgery at Englewood Hospital in Englewood, New Jersey performed by Dr. Fred Lee.

14. During the surgery, Dr. Lee implanted the following components in Plaintiff's right femur, all of which were manufactured, designed, sold, and distributed by Defendants: (a) Trigen Intertan Nail, Ref. 71675201, Lot # 13GT32740; (b) Internal Hex Captured Screw, Ref. 71642230, Lot # 13CT29438; (c) Trigen Intertan Integrated-Interlocking Lag Screw, Ref. 71677105, Lot # 11HM13093. Dr. Lee obtained these components from the Defendants' agent and product representative Johnny Swanson in the operating room.

15. Following discharge from Englewood Hospital, Plaintiff was transferred to the Prospect Heights Care Center in Hackensack, New Jersey on September 25, 2013.

16. On October 24, 2013, while preparing for bed at Prospect Heights Care Center, Plaintiff was standing next to his bed fixing the sheets when he experienced a sharp pain to his right hip.

17. An x-ray taken at Prospect Heights on the following morning revealed that Plaintiff had suffered a fracture to the screw component of his orthopedic device and a re-fracture of his femoral neck.

18. An ambulance transported Plaintiff back to Englewood Hospital for evaluation and orthopedic care.

19. On confirmation of the Product failure, an event none of his healthcare providers could ever recall witnessing before, Plaintiff has surgery on October 28, 2013 by Dr. Asit Shah to remove the failed intramedullary nail and to undergo a total hip replacement.

20. During the October 28, 2013 surgery, Dr. Shah noted a failure of the hardware and a broken screw and failure of the fracture site.

21. The pathology report of explanted bone and device components described a femoral neck with an embedded piece of metal rod extending out the distal end, the metal rod showing an irregular end.

22. Within a few months of Plaintiff's spontaneous device failure, Defendants began urgent product recalls worldwide in April 2014 to notify customers of manufacturing defects in its Trigen Intertan Nail Products, devices identical to those originally implanted in Plaintiff on September 21, 2013.

23. At the time of Plaintiff's implant surgery on September 21, 2013, the implant products had remained within the exclusive custody and control of Defendants and their agents and servants from the time of manufacture up until the time they were surgically implanted in Plaintiff.

24. On information and belief, Defendants' Product failed due to a single acute break in the interlocking screw rather than though metal fatigue or so-called micro-motion, likely resulting from a design or manufacturing defect during casting, machining or finishing the Product, the presence of foreign contaminants or inclusions within the finished metal, a manufacturing error causing the screw to be inserted too deep in the companion nail component, or a manufacturing error that resulted from malpositioning of the screws into the openings in the

intramedullary nail. Plaintiff contends that these facts will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

25. On information and belief, Defendants' Product failed due to a systemic design error or errors in quality control or manufacturing technique that failed to identify substandard metal castings or blanks, or otherwise introduced a design fault into the components that increased the likelihood of component breakage in the absence of trauma or excessive biomechanical stress. Plaintiff contends in the alternative that these facts will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

26. At no time did anyone suggest to Plaintiff that the Defendants' Product intended to repair his fractured hip was itself at excessive risk of spontaneous breakage.

27. On information and belief, Plaintiff contends that Defendants, through their agents, servants and/or employees designed, developed, manufactured, tested, packaged, promoted, advertised, marketed, distributed, labeled, and sold the Trigen Intertan Nail and components without making proper and sufficient tests to determine the dangers thereof, and without sufficiently warning the public and the medical community of the risks inherent in its use, as well as the dangers, and side-effects inherent in the device. Plaintiff contends in the alternative that these facts will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

28. Defendant acted intentionally, purposely, recklessly, and/or negligently when advertising, marketing and recommending use of the Trigen Intertan Nail as a safe and effective device without sufficient warning of its dangerous propensities; represented that the Trigen Intertan Nail was safe for implantation and for its intended purpose, when in fact it was unsafe; and otherwise failed to appropriately warn users, including Plaintiff and the medical community of the dangers and side-effects inherent in the Trigen Intertan Nail. Defendant also acted intentionally, purposely, recklessly and/or negligently by failing to conduct sufficient, adequate and appropriate testing to determine whether or not the Trigen Intertan Nail was safe for its

intended use. . Plaintiff contends in the alternative that these facts will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

FIRST CAUSE OF ACTION OF STRICT LIABILITY AGAINST DEFENDANT SMITH & NEPHEW, INC.

29. That at all relevant times hereinafter mentioned, Defendant designed, manufactured, assembled, distributed, and/or otherwise released into the stream of commerce the subject Trigen Intertan Nail implanted in Plaintiff, which was expected by this Defendant to reach, and in fact reached, the Plaintiff, without substantial change in the condition in which it was designed, manufactured, assembled, distributed and sold.

30. That at all relevant times hereinafter mentioned, Defendant acted as wholesaler, distributor or retailer, or otherwise released into the stream of commerce of the subject Trigen Intertan Nail implanted in Plaintiff, which was expected by this Defendant to reach, and in fact reached, the Plaintiff, without substantial change in the condition in which it was designed, manufactured, assembled, distributed and sold.

31. That Said Trigen Intertan Nail was defective and unreasonably dangerous at the time of its design, manufacture, assembly, distribution and sale by this Defendant, in that the device was designed, manufactured, constructed, assembled, sold, distributed with contaminant inclusions in the metal components, incorrectly machined screw threads, incorrectly positioned joint holes, or other manufacturing errors or defects that deviated from the norm, as required to meet ordinary consumer expectations and reasonable standards of care given the potential uses and misuses reasonably foreseeable by this Defendant.

32. That Defendant's Product further failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the Defendant, and the risk of danger in the design and manufacture outweighed any potential benefits thereof.

33. That on or before September 21, 2013, Plaintiff had Defendant's Product

implanted in his hip in an effort to repair a hip fracture.

34. That on or about October 24, 2013, Plaintiff was standing next to his bed fixing the sheets.

35. That on said date, Plaintiff felt a sharp pain in his hip.

36. That Plaintiff sustained catastrophic injury in the form of a fracture of Defendant's Product and a re-fracture of his femur.

37. That because of the aforesaid defective and unreasonably dangerous condition of Defendants' product, Plaintiff sustained serious, severe and painful personal injuries.

38. The manufacturing defect in Defendant's product was a direct and proximate cause of the defective and unreasonably dangerous condition of this Defendant's product.

WHEREFORE, Plaintiff demands judgment against Defendant for damages as more fully set forth below, in an amount in excess of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the cost of this action.

SECOND CAUSE OF ACTION OF NEGLIGENCE AGAINST DEFENDANT SMITH & NEPHEW, INC.

39. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

40. Defendant designed, manufactured, assembled, distributed, and/or otherwise released into the stream of commerce the subject Trigen Intertan Nail, which was expected by this Defendant to reach, and in fact reached, the Plaintiff without substantial change in the condition in which it was designed, manufactured, assembled, distributed and sold.

41. Defendant wholesaled, distributed, sold, retailed, and/or otherwise released into

the stream of commerce the subject Product which was expected by these Defendants to reach, and in fact reached, the Plaintiff without substantial change in the condition in which it was designed, manufactured, assembled, distributed and sold.

42. As such, Defendant owed Plaintiff, as a foreseeable ultimate consumer and user of its product who was within the zone of risks reasonably foreseeable by the Defendant, a duty of reasonable care, in the design, manufacture, assembly, distribution and sale of the product in a reasonably safe condition for its intended and foreseeable use.

43. Defendant breached said duty and was negligent in designing, manufacturing, assembling, distributing, and/or otherwise releasing into the stream of commerce the subject Product that spontaneously broke and re-fractured Plaintiff's leg, in that said Product was designed, manufactured, constructed, sold, distributed with a manufacturing defect, a systemic design flaw that increased the risk of breakage or inadequate or nonexistent warning as to the risks associated with the Product's use, as required to meet ordinary consumer expectations and reasonable standards of care given the potential uses and misuses reasonably foreseeable by Defendant, and said facts were known to or in the exercise of reasonable care should have been known to Defendant at the time it designed, manufactured, assembled, distributed and/or otherwise released into the stream of commerce the subject product.

44. Spontaneous breakage of the Product was a foreseeable occurrence of which this Defendant had actual or constructive notice from prior reported incidents, consumer product safety and/or supplier warnings, recalls and/or tests, and Defendants were further negligent in failing to convey and warn foreseeable vendors, users, and consumers of its product, including Plaintiff.

45. That because of the aforesaid defective and unreasonably dangerous condition of Defendants' product, Plaintiff sustained serious, severe and painful personal injuries as described above.

46. On October 24, 2013, Plaintiff re-fractured his leg as a direct and proximate cause

of the defective and unreasonably dangerous condition of this Defendant's product and negligence.

WHEREFORE, Plaintiff demands judgment against Defendant for damages as more fully set forth below in an amount of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the costs of this action.

THIRD CAUSE OF ACTION OF WILLFUL MISCONDUCT AGAINST DEFENDANT SMITH & NEPHEW, INC.

47. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

48. That at all relevant times, Defendant knew that its Trigen Intertan Nail and similar models created a foreseeable risk of spontaneous breakage due to manufacturing errors or systemic design errors in the manufacturing process.

49. That Defendant continued to manufacture, market, sell, and distribute its Product that caused the Plaintiff's injuries.

50. That Despite this knowledge and with full awareness that more injuries were virtual certainties, Defendant continued to manufacture, market, sell, and distribute the Product in flagrant and willful disregard for the safety of orthopedic patients, including Plaintiff.

51. That Defendant's willful misconduct in manufacturing and selling deliberately an unreasonably dangerous product that was not fit, suitable or safe for use justifies the imposition of punitive or exemplary damages against Defendants in accordance with the laws of the States of New Jersey and New York.

52. That In light of Defendant's willful misconduct, punitive damages are the only deterrent to prevent future misconduct and to protect consumers from the misconduct and

financial predations of companies like Defendant.

WHEREFORE, Plaintiff demands judgment against Defendant for punitive damages as more fully set forth below in an amount of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the costs of this action.

FOURTH CAUSE OF ACTION OF PRODUCT LIABILITY FAILURE TO WARN AGAINST DEFENDANT SMITH & NEPHEW, INC.

53. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

54. Defendant had actual or constructive knowledge of the risk to orthopedic patients posed by the fracture risk of its Product.

55. This same risk had been identified for other of Defendants' products and all products of similar design.

56. This actual or constructive knowledge imposed a duty on the Defendant to advise consumers of this risk.

57. Defendant should have warned consumers, including Plaintiff, that there was an increased risk of breakage of its Product when used as intended.

58. Despite this actual or constructive knowledge of this unreasonable risk, Defendant failed to warn consumers, including Plaintiff, of the danger its Product posed.

59. That because of the negligence of defendant, Plaintiff sustained serious, severe and painful personal injuries as described above.

60. On October 24, 2013, Plaintiff suffered serious personal injury as a direct and

proximate cause of the negligence of the Defendant in designing, selling and distributing the Product in a defective and unreasonably dangerous condition.

61. Defendants' failure to warn consumers, including Plaintiff, of the risk to orthopedic patients was a proximate cause of the Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendant for damages as more fully set forth below in an amount of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the costs of this action.

FIFTH CAUSE OF ACTION OF BREACH OF IMPLIED WARRANTY AGAINST DEFENDANT SMITH & NEPHEW, INC.

62. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

63. The Trigen Intertan Nail was not reasonably fit, suitable or safe for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner.

64. The Product was not minimally safe for its intended purpose because it was designed, manufactured, constructed, sold with a manufacturing flaw, systemic design defect or inadequate or absent warning about its risk of spontaneous fracture.

65. The Product was not minimally safe for its intended purpose because of one or more of these defects as described above.

66. At all relevant times, Plaintiff used the Product for the purpose and in the manner intended by Defendant.

67. Plaintiff by the use of reasonable care would not have discovered the breached

warranty and realized its danger.

68. Defendant's breach of the implied warranty was a substantial factor in bringing about Plaintiff's injuries.

69. As a direct result of Defendant's conduct, Plaintiff suffered severe and painful personal injuries as described above.

WHEREFORE, Plaintiff demands judgment against Defendant for damages as more fully set forth below in an amount of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the costs of this action.

SIXTH CAUSE OF ACTION OF BREACH OF EXPRESS WARRANTY AGAINST DEFENDANT SMITH & NEPHEW, INC.

70. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

71. Defendants advertised, labeled, marketed and promoted its Product, representing the quality to Plaintiff and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Product would conform to the representations. More specifically, Defendants represented that the Trigen Intertan Nail was safe and effective for use by individuals such as Plaintiff.

72. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer that related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations

of fact or promises.

73. The Product did not conform to the representations made by Defendant in that the Product was not safe and effective generally and was not safe and effective for use by individuals such as Plaintiff.

74. At all relevant times, Plaintiff used the Product for the purpose and in the manner intended by Defendant.

75. Plaintiff by the use of reasonable care would not have discovered the breached warranty and realized its danger.

76. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

77. As a direct result of Defendant's conduct, Plaintiff suffered serious severe painful injuries as described above.

WHEREFORE, Plaintiff demands judgment against Defendant for damages as more fully set forth below in an amount of the jurisdictional limits of this Honorable Court, together with prejudgment interest on all sums for which such interest is recoverable by law, and the costs of this action.

SEVENTH CAUSE OF ACTION FOR VIOLATION OF CONSUMER PROTECTION STATUTE AGAINST DEFENDANT SMITH & NEPHEW, INC.

78. Plaintiff readopts and realleges all preceding paragraphs with the same force and effect as if the same were set forth herein fully and at length and further alleges:

79. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statute listed below when it failed to adequately warn consumers and the medical community of the safety risks associated with the Trigen Intertan Nail, including that the Trigen Intertan Nail was adulterated, was manufactured in violation of its PMA specifications, and could prematurely fracture. As a direct result of Defendant's deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, mental anguish and other compensable injuries.

80. Defendant engaged in unfair competition and/or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law§§ 349 *et seq.* and 350 *et seq.*

81. The actions and failure to act of Defendant, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of the Trigen Intertan Nail to fracture and fail prematurely and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendant of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendant in violation of the consumer protection statute listed above.

82. Plaintiff and Plaintiff’s medical providers relied upon Defendant's misrepresentations and omissions in selecting the Trigen Intertan Nail for Plaintiff’s use. At the time Plaintiff was implanted with the defective Trigen Intertan Nail, the Defendant was aware that the Trigen Intertan Nail failed to conform to manufacturing specifications resulting in an increased risk to premature fracture.

83. Plaintiff's Trigen Intertan Nail fractured prematurely because of a manufacturing defect or systemic design defect.

84. By reason of the unlawful acts engaged in by Defendant, Plaintiff has suffered ascertainable loss and damages.

85. As a direct and proximate result of Defendant's wrongful conduct, including the defective and dangerous manufacture and inadequate warnings of the Trigen Intertan Nail, Plaintiff's device prematurely fractured, requiring revision surgery. Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, instability and loss of balance, immobility, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

86. As a direct and proximate result of Defendant's conduct, Plaintiff suffered and will continue to suffer personal injury, economic loss, pecuniary loss, mental anguish and other compensable injuries.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys ' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Punitive damages;

4. Double or triple damages as allowed by law;

5. Reasonable attorneys' fees;

6. The costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues.

Dated:

Respectfully submitted,

Terrence Smith [8297]
Davis, Saperstein & Salomon P.C.
375 Cedar Lane
Teaneck, NJ 07666
Tel.: (201) 907-5000
Fax: (201) 692-0444
tsmith@dsslaw.com
Attorneys for Plaintiff Jacob Leibowitz

CERTIFICATE OF SERVICE
I hereby certify that on 11/7/2014 I caused the foregoing to be served via the Court's ECF System on all counsel.

Terrence Smith